

# Hisamitsu Pharmaceutical Co., Inc.

## Q2 FY02/2014 Results

This presentation material contains information that constitutes forward-looking statements. Such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and actual results may differ from those in the forward-looking statements as a result of various factors including changes in material circumstances.

Hisamitsu Pharmaceutical Co., Inc.

Oct. 9<sup>th</sup>, 2013

Patch and Care of People around the World

### Consolidated PL

Unit:¥ million

	Q2 FY02/13	Q2 FY02/14	YoY	Consolidated / Non-consolidated
Net sales	71,932	77,382	+7.6%	1.20
CoGS	26,013	28,018	+7.7%	
as a % of sales	36.2%	36.2%		
SG&A costs	32,669	36,900	+13.0%	
Advertising costs	5,498	6,638	+20.7%	
R&D spending	6,278	6,570	+4.7%	
Others	20,893	23,692	+13.4%	
Operating profits	13,248	12,462	-5.9%	0.80
Recurring profits	16,481	16,856	+2.3%	1.03
Net profits	9,334	13,681	+46.6%	1.00

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# Summary of Profit and Loss

Unit:¥ million

	① Q2 FY02/13	② Q2 FY02/14	②-①	Main factor
<b>Net sales</b>	<b>71,932</b>	<b>77,382</b>	<b>+5,450</b>	
Rx Business	49,778	49,696	-82	•[Last year] Increase in sales of most products as a reaction, before National Health Insurance price reduction.
OTC Business	9,335	10,889	+1,554	•Increase in sales of a new product and major products.
Intl Business	2,665	3,708	+1,043	•Increase in sales of major products.
Noven	6,249	8,388	+2,139	•Influence of the exchange. •Increase in sales of major products.
Others	3,905	4,701	+796	•Increase in sales of overseas subsidiaries.
CoGS	26,013	28,018	+2,005	•Increase in Net sales.
as a % of sales	36.2%	36.2%	+0.0%	•Change of sales structure.
SG&A costs	32,669	36,900	+4,231	•Increase in SG&A costs of Noven. •Influence of the exchange.
<b>Operating profits</b>	<b>13,248</b>	<b>12,462</b>	<b>-786</b>	
Non-operating balance	3,233	4,393	+1,160	•Equity-method investment profits of Noven. •Foreign exchange gain.
<b>Recurring profits</b>	<b>16,481</b>	<b>16,856</b>	<b>+375</b>	
Extraordinary balance	-455	4,992	+5,447	•License fee (Distribution agreement).
<b>Net profits</b>	<b>9,334</b>	<b>13,681</b>	<b>+4,347</b>	

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# Non-consolidated PL

Unit:¥ million

	Q2 FY02/13	Q2 FY02/14	YoY
<b>Net sales</b>	<b>61,779</b>	<b>64,293</b>	<b>+4.1%</b>
Rx Business	49,778	49,696	-0.2%
OTC Business	9,335	10,889	+16.6%
Intl Business	2,665	3,708	+39.1%
CoGS	20,513	21,484	+4.7%
as a % of sales	33.2%	33.4%	
SG&A costs	26,830	27,214	+1.4%
Advertising costs	5,138	5,234	+1.9%
R&D spending	4,993	4,679	-6.3%
Others	16,699	17,301	+3.6%
<b>Operating profits</b>	<b>14,435</b>	<b>15,594</b>	<b>+8.0%</b>
<b>Recurring profits</b>	<b>14,834</b>	<b>16,298</b>	<b>+9.9%</b>
<b>Net profits</b>	<b>8,643</b>	<b>13,620</b>	<b>+57.6%</b>

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# Noven PL

	Unit: ¥ million			Unit: \$ thousand		
	Q2 FY02/13	Q2 FY02/14	YoY	Q2 FY02/13	Q2 FY02/14	YoY
<b>Net sales</b>	<b>6,249</b>	<b>8,388</b>	<b>+34.2%</b>	<b>78,338</b>	<b>87,475</b>	<b>+11.7%</b>
Daytrana <sup>®</sup>	2,483	3,240	+30.5%	31,126	33,789	+8.6%
Vivelle-Dot <sup>®</sup>	2,130	2,770	+30.0%	26,699	28,894	+8.2%
Minivelle <sup>®</sup>	-	783	-	-	8,171	-
Noven Therapeutics	825	811	-1.7%	10,350	8,458	-18.3%
Others	811	784	-3.3%	10,163	8,163	-19.7%
CoGS	3,659	4,548	+24.3%	45,868	47,427	+3.4%
as a % of sales	58.6%	54.2%		58.6%	54.2%	
SG&A costs	4,052	7,290	+79.9%	50,793	76,026	+49.7%
R&D spending	1,291	1,899	+47.1%	16,192	19,805	+22.3%
Others	2,760	5,391	+95.3%	34,601	56,221	+62.5%
<b>Operating profits</b>	<b>-1,461</b>	<b>-3,450</b>	<b>-</b>	<b>-18,323</b>	<b>-35,978</b>	<b>-</b>
Nonoperating balance	2,917	3,996	+37.0%	36,567	41,672	+14.0%
Equity in earnings of Novogyne	3,723	5,555	+49.2%	46,678	57,934	+24.1%
Amortization of fair value adjustment to investment in Novogyne	-815	-1,712	-	-10,223	-17,855	-
<b>Recurring profits</b>	<b>1,455</b>	<b>546</b>	<b>-</b>	<b>18,243</b>	<b>5,693</b>	<b>-</b>
<b>Net profits</b>	<b>1,018</b>	<b>475</b>	<b>-53.3%</b>	<b>12,770</b>	<b>4,962</b>	<b>-61.1%</b>
Exchange rate (¥/USD)	¥79.78	¥95.90				

\*Noven Therapeutics: Pexeva<sup>®</sup>, Lithobid<sup>®</sup>, Stavzor<sup>®</sup>

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## Sales results of major products

Unit: ¥ million

		Q2 FY02/13	Q2 FY02/14	YoY
Ethical drugs	Mohrus <sup>®</sup> Tape	39,391	38,939	-1.1%
	Mohrus <sup>®</sup> Pap	4,164	3,679	-11.6%
	Fentos <sup>®</sup> Tape	1,699	1,757	+3.4%
	Norspan <sup>®</sup> Tape	588	903	+53.6%
	Naboal <sup>®</sup>	936	750	-19.9%
	Estrana <sup>®</sup> Tape	626	644	+2.9%
	Neoxy <sup>®</sup> Tape	-	493	-
	Daytrana <sup>®</sup>	2,483	3,240	+30.5%
	Vivelle-Dot <sup>®</sup>	2,130	2,770	+30.0%
	Minivelle <sup>®</sup>	-	783	-
	Noven Therapeutics	825	811	-1.7%
	OTC drugs	Salonpas <sup>®</sup> products	3,291	3,795
Salonship <sup>®</sup> products		1,922	2,057	+7.0%
Feitas <sup>®</sup> products		1,738	1,570	-9.7%
Butenlock <sup>®</sup> products		1,046	1,407	+34.5%
Allegra <sup>®</sup> FX		-	1,186	-
Air <sup>®</sup> Salonpas <sup>®</sup> products		1,150	1,150	0.0%

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## 6. Revision of the consolidated earnings forecast

Unit:¥ million

Q2 FY02/14	Previous Forecast (A)	Revised Forecast (B)	Difference (B)-(A)	Actual
<b>Net Sales</b>	76,800	77,300	<b>+500</b>	77,382

**Intl Business + Overseas Subsidiaries: +700, OTC Business: +600, Rx Business: -800**

CoGS	27,800	28,000	+200	28,018
<b>SG&amp;A costs</b>	39,000	36,900	<b>-2,100</b>	36,900

**R&D spending: -1,100, Advertising costs: -400, Others: -600**

<b>Operating Income</b>	10,000	12,400	<b>+2,400</b>	12,462
<b>Non-operating balance</b>	3,600	4,400	<b>+800</b>	4,316

**Equity-method investment profits.: +600, Foreign exchange gain: +200**

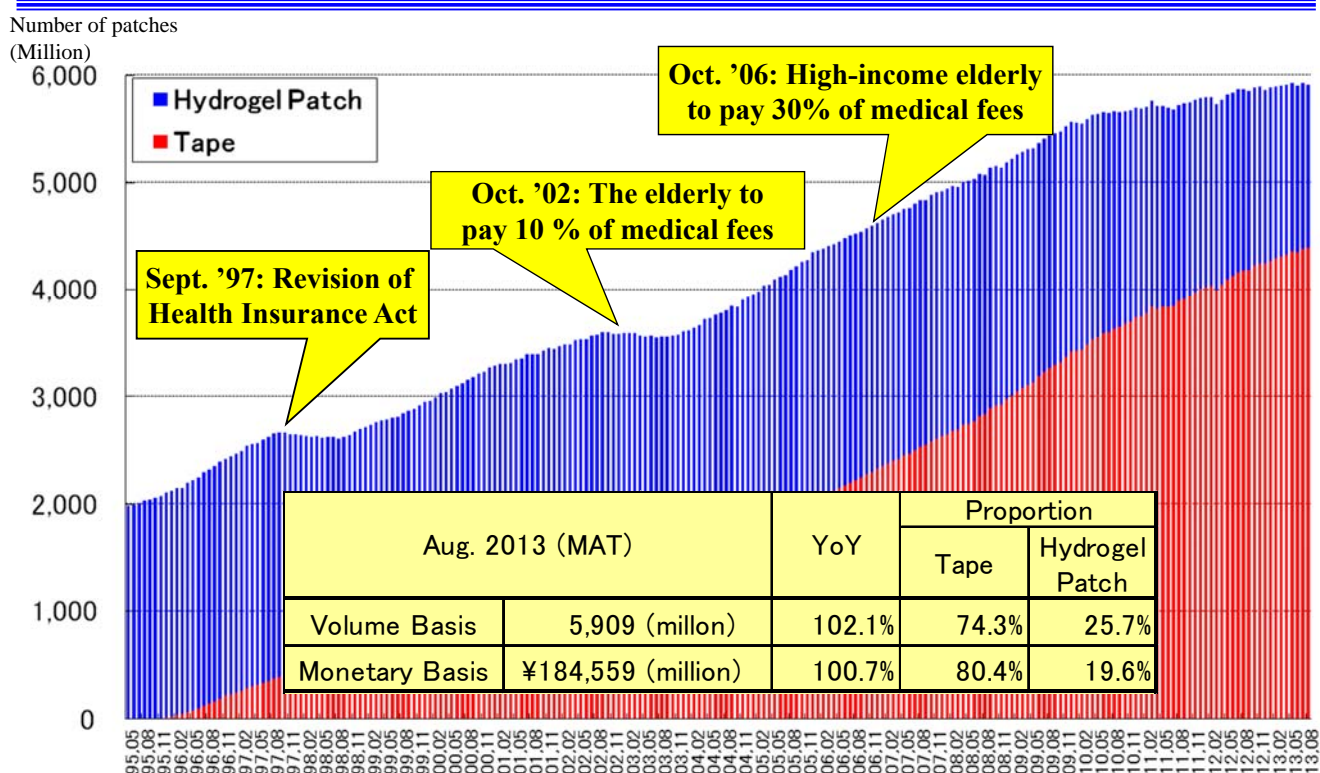
<b>Recurring profits</b>	13,600	16,800	<b>+3,200</b>	16,778
Net profit before tax	18,600	21,700	+3,100	21,773
<b>Quarterly Net Income</b>	11,500	13,600	<b>+2,100</b>	13,606
Exchange rate (¥/USD)	¥94.00	¥95.90	—	¥95.90

\* We have no plan to revise the consolidated earnings forecast for the full fiscal year.

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## Trends of second-generation non-steroidal anti-inflammatory patch market (volume-basis)

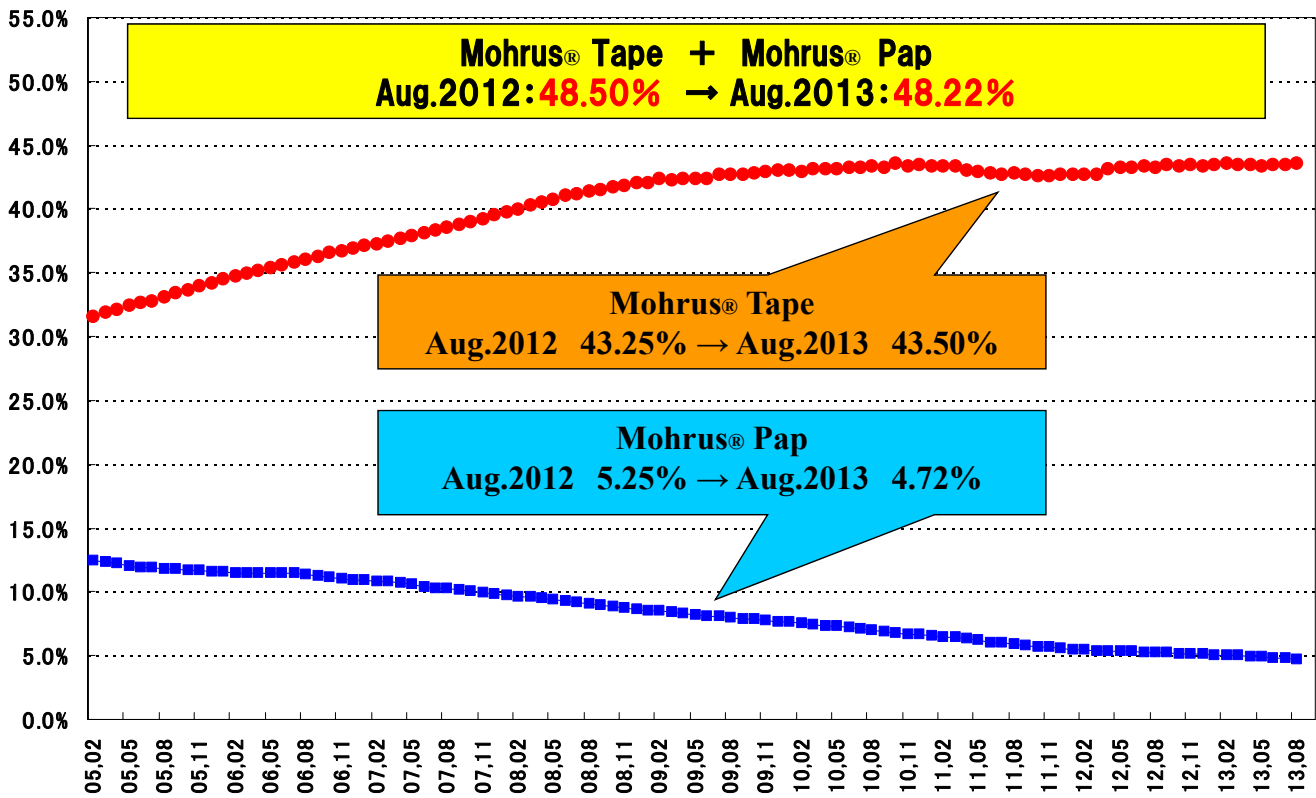


Source: IMS, JPM data (~Aug. 2013) \*No reproduction or republication without written permission.

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# Changes in shares of second-generation non-steroidal anti-inflammatory patch



Source: IMS, JPM data (~ Aug. 2013) \*No reproduction or republication without written permission.

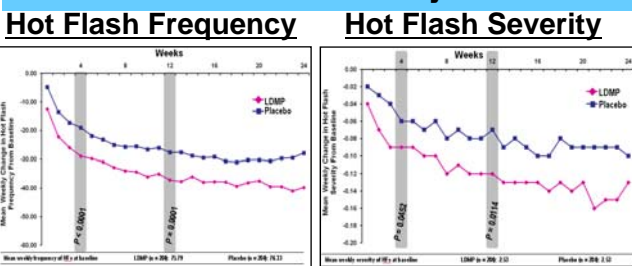
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## Brisdelle™ : Follow-Up(1)

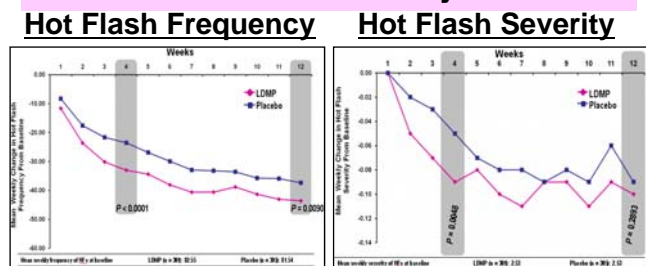
### Outline of the Phase III Clinical Study

- (1) Content of the Study: 2 Studies (24-week study and 12-week study)
- (2) Design of the Study: double-blind placebo-controlled study
- (3) Primary endpoint: Mean changes in frequency and severity of vasomotor symptoms (VMS)
- (4) Evaluation point: 4 weeks and 12 weeks after the initiation

#### <24-Week Study>



#### <12-Week Study>



- The 12-week and 24-week studies achieved statistical significance in all primary endpoints except for mean changes in severity at the evaluation point of 12 weeks after the initiation in the 12-week study.
- Therapeutic effects were maintained for 24 weeks.

### Indication

The relief of moderate to severe vasomotor symptoms (VMS) associated with menopause

### Dosage and Administration

1 capsule per day at bedtime

# Brisdelle™ : Follow-Up(2)

## ■ Potential of Brisdelle™

### (1) Assumed Price (per capsule)

- Similar to that of **Brand-name antidepressants (paroxetine)**

### (2) Assumed number of patients to whom it is prescribed

- **Approximately 350,000 people** (at its peak)

### (3) Assumed duration of the exclusive marketing right

- **Approximately 9 years** (until February 12 2023)



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# Brisdelle™ : Follow-Up(3)

## ■ Key Launch Milestones

### (1) June 28:

FDA approval was obtained

“FDA approves the first non-hormonal treatment for hot flashes associated with menopause.”

### (2) September 18:

Menopause Publication

- Maximize awareness of Brisdelle Phase III Pivotal Data via *Menopause* journal article.

### (3) October 9 – 12:

The presentation will be held at the 2013 Annual Meeting of the North American Menopause Society.

### (4) November :

Brisdelle™ is scheduled to be available on the market

Brisdelle Approved by FDA June 28, 2013

Media Coverage Reached More Than 64 million People

<p>105 Online/Print Stories Including...</p>	<p>142 Broadcast Stories Including...</p>	<p>Social Media</p> <p>889 posts Reaching: 4,300,000 People</p> <p>@katiecouric: FDA approves Brisdelle, the first non-hormonal treatment for hot flashes associated with menopause.</p> <p>@ThePharmaLetter: Noven's Brisdelle is first non-hormonal treatment for menopausal hot flashes to be approved by FDA.</p>
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Exhibit booth (image)



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# R&D Pipeline

Stage	Theme	Target	Dosage Form	Characteristics	Next Step
Approval	Brisdelle™ (LDMP)	USA	Oral	Moderate to severe VMS associated with menopause (Hot flashes)	Planned Launch in Nov. 2013
Filed (ANDA)	HP-1010	USA	Adhesive skin patch	Relief of pain associated with post-herpetic neuralgia	No disclosure
Filed (ANDA)	HP-1030	USA	Adhesive skin patch	Alzheimer's disease	No disclosure
Filed	Estrana® Tape 0.72mg (Additional Indication, dosage and administration)	JPN	Adhesive skin patch	Hypoestrogenism due to causes, such as hypogonadism	To be approved in FY13
Filed	HFT-290 (Additional Indication of FENTOS® Tape)	JPN	Adhesive skin patch	Relief of non-malignant chronic pain	To be approved in FY14
Phase3 being prepared	ATS	USA	Adhesive skin patch	Attention Deficit Hyperactivity Disorder (ADHD)	Phase3 in FY13
Phase2	HP-3060	JPN	Adhesive skin patch	Allergic rhinitis	Phase3 in FY14
Phase2	HP-3000	JPN	Adhesive skin patch	Parkinson's disease	Phase3 in FY15
Phase2	HP-3000	JPN	Adhesive skin patch	Idiopathic restless legs syndrome	Phase3 in FY15

※Yellow-highlighted parts are changes from the previous announcement made on Jul.10<sup>th</sup>, 2013

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## Aiming at improving the QOL of people around the world

Q2 FY02/2014 Results

Oct. 9th, 2013

Hisamitsu Pharmaceutical Co., Inc.

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